PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/679,563 Confirmation No.: 3117
Applicant : Gary B. McAlister
Filed : October 6, 2003
TC/A.U. : 3733
Examiner : Comstock, David C.
Title : RETRIEVAL DEVICE MADE OF PRECURSOR ALLOY CABLE
Docket No. : 1001.1658102
Customer No. : 28075

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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By JoAnn Lindman
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Appellants have carefully reviewed the Final Office Action mailed October 29, 2008 and the Advisory Action mailed January 13, 2009. Currently, claims 38-58 are pending in the application and have been rejected by the Examiner. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

In the Final Office Action mailed October 29, 2008, the Examiner has rejected claims 38-44 and 46-57 under 35 U.S.C. 102(b) as being anticipated by Gibbs et al. (U.S. Patent No. 4,425,908), hereinafter Gibbs (cited by Applicant), or, alternatively under 35 U.S.C. 103(a) as being unpatentable over Gibbs. Further, claims 45 and 58 have been rejected under §103(a) over Gibbs.

A rejection under 35 U.S.C. 102/103 can be made when the prior art seems to be identical except that the prior art is silent as to an inherent characteristic; however the Examiner must provide a rational or evidence tending to show inherency.

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)
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> "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)
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> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (Emphasis in the original.)

The Examiner appears to rely upon similarity between the elemental compositions of the nickel-titanium alloys employed by Gibbs and the alloys of the pending application to ensure that the alloys will comprise the same claimed characteristics. This ignores the well known and art recognized differences between the mechanical properties of nickel-titanium alloys having identical elemental compositions, but different thermal histories and thus different phase compositions. Indeed, a single sample of nickel-titanium wire (compositionally identical to itself) may be either "pseudoelastic" or "superelastic" and may be converted from one state to the other and back repeatedly by appropriate thermal processing. Accordingly, elemental composition does not suffice to ensure that a first nickel-titanium alloy comprises the same mechanical characteristics as a second sample having identical elemental composition or that a nickel-titanium alloy is inherently either "pseudoelastic" or "superelastic".

Although the Examiner has asserted that the device of Gibbs is not heat treated until *after* the basket portion is formed, the disclosure of Gibbs does not appear to support that assertion, but rather merely appears to state that it is heated after the basket is formed without commenting on heat treatments which may have occurred in processing the raw wire or during fabricating the cable from which the basket is formed. Gibbs makes multiple references to soldering as steps in the fabrication of the extraction basket prior to shaping:

> "Extraction wires are joined by soldering stainless steel strands 12 together at one end at push rod/cable solder joint 73 and attached to push rod 72 at joint 73. At the distal end, extraction wires 77a-d are also joined by soldering at stainless steel strands 12 together at distal basket hub soldering joint 76. Extraction wires 77a-d are then also joined at a set position a set distance from the distal end of extraction wires 77a-d by soldering stainless steel strands 12 together at proximal basket hub solder joint 75." (Col. 3, lines 26-35.)

The fact that the nickel-titanium alloy has been heated at one point does not inherently provide information regarding the phase composition of the alloy prior to that heating step. For Gibbs to inherently disclose formation of a wire basket in a pseudoelastic or martensitic state requires that the thermal history of the nickel-titanium wire from which the stainless steel stranded cable is formed be known. Nothing in Gibbs appears to indicate that the nickel-titanium wire from which the stainless steel stranded cable is formed is anything other than superelastic. Instead, Gibbs states: "As a shape memory material, nitinol central wires 11 and 21 have the characteristic of superelasticity whereby they exhibit a superelastic tendency to retain the shape in which they are formed when heat is applied to a suitable presorting temperature." which appears to indicate that the stranded cables of Figs. 1A, 1B, 2A, and 2B from which the device is formed comprises a superelastic nickel-titanium wire prior to the formation step.

In the alternative, the use of soldering, presumably silver soldering, indicates that temperatures of 590-870 °C may have been used to join the stainless steel/ nickel-titanium wire cables (at 73, 76 and 75). Common tin-lead soft solders, less commonly used in medical applications melt at 183 °C or 188 °C. For this reason, the nickel-titanium wire cable of Gibbs appears to have been heated, at least once, to a temperature well above the martensite to austenite transition temperature range which varies for different compositions and has been reported to be between about -50 °C to 166 °C with transition temperatures of the order of 0-115 °C commonly available commercially. The soldering step occurs before the forming step disclosed at column 3, lines 36-45 of Gibbs. There does not appear to be any indication that the soldered intermediate construct is allowed to cool below the transition temperature between forming and setting the final shape and there does not appear to be a technical reason why cooling at that point would be necessary, desirable, or cause the nickel-titanium alloy to revert to a pseudoelastic or martensitic phase composition. Gibbs appears to disclose cooling the device only after forming and heating and before placement in a retaining cannula. Accordingly, in at least some variations of the manufacturing process disclosed by Gibbs, the starting material for creating the cable and/or forming the resulting cable is not martensite and not pseudoelastic as would be required for either an inherency argument or an obviousness rejection. Further, the medical device of the pending claims is pseudoelastic and martensitic while that produced by Gibbs is explicitly superelastic. Neither the manufacturing intermediate of Gibbs nor the finished superelastic device appears to be inherently and/or obviously pseudoelastic or martensitic as required by the pending independent claims.

It is particularly relevant that Gibbs consistently refers to the wires of his wire basket as "superelastic". Nowhere does Gibbs appear to indicate that his nickel-titanium alloy wires are ever anything other than a superelastic phase composition and nothing in Gibbs appears to require, or even suggest, that the wires are not in a superelastic state throughout the process. By contrast, Applicants specifically claims a device in which the nickel-titanium alloy is pseudoelastic or martensitic (not superelastic) before and after fabrication. Applicant forms his device from a non-superelastic precursor alloy and takes pains to ensure that the alloy remains in the pseudoelastic state. Further, Applicant specifically warns against heat treating the cable such that the precursor alloys are converted to superelastic materials (page 14, lines 2-5) and notes that the use of precursor alloys enables the device to be manufactured without the heat treatment processes (page 14, lines 8-10) to which the devices of Gibbs are specifically subjected and upon which Gibbs depends for the superelastic properties that he desires.

Accordingly, Gibbs does not appear to disclose *each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference* as required for anticipation under §102 and the Examiner has failed to provide a rational or evidence tending to show inherency under §102/103. Although it is conceivable that Gibbs may created a pseudoelastic construct at some point during his fabrication process, it appears highly unlikely that it was present following the basket forming process and prior to heating, and certainly not inherent that he has done so as would be required to sustain a rejection under §102/103. Further the explicitly superelastic device of Gibbs is not pseudoelastic or martensitic as required by independent claims 38, 47, and 53. Thus Gibbs fails to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness for a rejection under §103 and Applicant respectfully requests that the rejections be withdrawn.

Additionally, for similar reasons as well as others, claims 39-46, 48-52, and 54-58, which depend from claims 38, 47, and 53 respectively, and include significant additional limitations thereto, are believed to be not anticipated by Gibbs and Applicant respectfully requests that the rejections be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03) In the alternative, it is believed that claims 39-46, 48-52, and 54-58, which depend from nonobvious independent claims 38, 47, and 53 respectively, are also nonobvious and Applicant respectfully requests that the rejections be withdrawn.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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